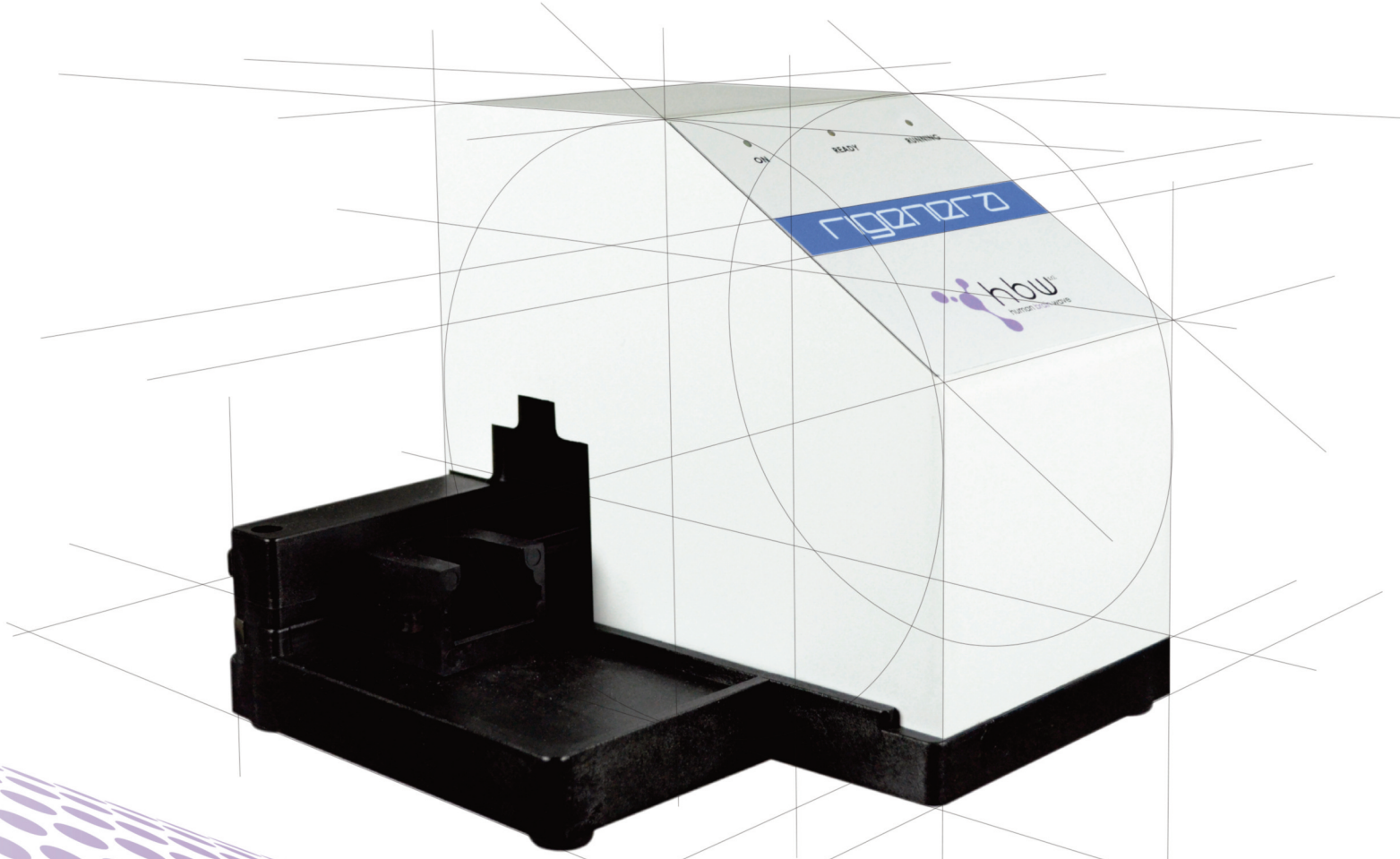
rigenera

MACHINE FOR MEDICAL APPLICATIONS OF CLINICAL REGENERATION



Rigenera Machine, code: 79210R
Rigeneracons, code: 79450S e 79350S

CE

hbw s.r.l.
human brain wave

Printed in **January 2013**

manufactured by:
CTSV Srl
Via Marco Polo, 28
10090 Bruino (TO)
ITALY

on exclusive behalf of:
Human Brain Wave Srl
registered office: Via Balangero, 6 - 10149 Torino
offices and laboratories: Via Pinerolo, 101 - 10060 Candiolo (TO)
Tel: +39 011 793.59.86 - R.M. +39 338.366.39.79
info@hbwsrl.com - www.hbwsrl.com

Machine pick-up date:

_____

This manual is divided into seven sections and each section has its symbol.

Section A - general information

General information important to know the machine **Biological Tissue Disgregator** are reported in this manual. Data for the exact identification of the apparatus are also provided. Responsibilities and requirements are clarified for operators and information provided for a safe use.

Section B - details and specifications

Technical characteristics of the **Biological Tissue Disgregator** are reported.

Section C - rules and safety devices

This section refers to all rules, regulations and information relating to security regarding both the operator and the equipment.

Section D - operator

Responsibilities and requirements for operators are specified and information for safe use are provided.

Section E - description of commands and tools

The various controls spread in machine are explained and illustrated.

Section F - instructions for use

How to use the machine is described and illustrated.

Section G - maintenance

It is reported everything related to the periodicity and maintenance interventions of the **Biological Tissue Disgregator**.

Topics

Section A - General Information

In this manual you will encounter symbols accompanied by text.
These symbols are intended to anticipate warnings or suggestions about to a given situation.

Warning

It is used when you want to provide operator guidance on methods or prohibited or recommended procedures.

Caution

It is used to alert the operator about conditions or situations that could be dangerous for the structure or load.

Danger

It is used to alert the operator about conditions or situations that could be dangerous for the operator or people in the proximity of the machine.

Identification of Biological Tissue Disintegrator

Identification label is placed on the device shell containing at least the following items:

1. model
2. serial number
3. manufacturer (CTSV)
4. CE mark

Information for users

In the following pages, the word "Manufacturer" refers to CTSV srl as manufacturer of the **Biological Tissue Disgregator**.

The instructions in this manual are those provided by the manufacturer.

Warning

The user must be aware of the following areas of responsibility:

Manufacturer of the Biological Tissue Disgregator
Responsible for the marketing of the product as well as it is originated from factory, as part of the intended use in the specific section B.

Warning

at the withdrawal of the Biological Tissue Disintegrator check the following points:
- the presence of the identification label of the **Biological Tissue Disgregator** with CE Mark (applied by the manufacturer).
- labels on the machine in the required language (country).
- the presence of the user manual in the required language.

Caution

The technical standards contained in this manual refer to the **Biological Tissue Disgregator** as it comes from the factory.

It is forbidden any welding, tampering with electrical equipment, replacement of parts with non-original parts, removal of cover and protection devices.

Maintenance must be carried out according to the requirements and periodicity described in section G of this manual.

Duties and responsibilities

Duties

In this context reference is made only to the tasks of the operator and inherent to the use of the **Biological Tissue Disgregator**, ranging from activation of the power circuit to maintenance.

The operator must therefore know the safety rules and the related devices and the use of controls.

Responsibility

The operator is directly responsible for the use and proper functioning of the **Biological Tissue Disgregator**, its maintenance and any action it plays in the context of the tasks listed above.

Transport and storage

Temperature (T): + 10 to +40 ° C.
Maximum relative humidity (% RH): 70%.
Atmospheric pressure (P): 50 to 106 Kpa.

Sezione B
Performance and technical data
B.01

Permitted Use

The intended use is to use as a **Biological Tissue Disgregator** to be employed in exclusive combination with devices **RIGENERACONS (REF: 79450S and 79350S)**; they are constituted of a plastic container into which there is a propeller which allows the mincing of tissue samples and has a grid **50 microns for the REF: 79450S** and **35 microns for the REF: 79350S** for the filtering of the disintegrated compound obtained. The **Biological Tissue Disgregator**, called **RIGENERA** and used only with containers **RIGENERACONS**, allows you to isolate stem cells obtainable from small portions of biological tissue; stem cells so obtained are collected and reinserted into the patient to allow the regeneration of tissues in defect.

It is forbidden to use other than as intended by the manufacturer.

Specifications

Power supply: 110/240 Vac ± 10% 60/50Hz
Temperature: +10 to +40 ° C
Maximum relative humidity: 65%
Power consumption: <0.1 A

Caution

The conditions of electrical safety are guaranteed even in conditions of use with relative humidity up to 85%.

General safety

It is responsibility of the operator to know the **Biological Tissue Disgregator** and keep it in efficiency.

If in doubt, refer to the user 's manual.
The use of **Biological Tissue Disgregator** is restricted to staff specially trained.

Requirements

The staff who use or run the **Biological Tissue Disgregator** must be competent and trained.
The term "training" refers to the following:
This manual should be read, studied and understood, and also the graphics and the attached patterns, labels and indication of danger.
Before starting any operation, the staff must be familiar with the use of controls and of their movements, having idling tests carried out.

Duties and Responsibilities

Duties

In this context reference is made only to the tasks of the operator and inherent to use of **Biological Tissue Disgregator**, ranging from activation of the power circuit, to maintenance.
The operator must, therefore, be fully familiar with the rules of safety and the use of controls.

Responsibility

The operator is directly responsible for the use and proper functioning of the **Biological Tissue Disgregator**, its maintenance and any action it plays in the context of the tasks listed above.

Sezione E
description of the device
E.01

Description of the device

BACK

FRONT

SIDE

Sezione E
description of the device
E.02

While you read the instructions for use look carefully at the illustrations.

1. **Switch** - On / Off
On: Move the switch on the symbol I
Off: Move the switch on the symbol 0

2. **Connector**

Before connecting the power cord to the power outlet make sure that the voltage is the one indicated on the recapitulative label

3. **Fuses** - 2 fuses 5x20 F 100 mA

4. **Recapitulative label**

5. **Green light** - power

6. **Yellow light** - ready

7. **Yellow light** – working

8. **Starting lever** - RUN / STANDBY
Run: Turn the lever on RUN
Standby: Turn the lever on STANDBY

9. **Loading slide**

Sezione F
instructions for use
F.01

Introduction

This chapter describes all the movements and the exact sequence of steps for a correct use of the **Biological Tissue Disgregator**.

Caution

The device must be plugged to a power outlet of the electrical power system equipped with protection conductor (earthing).
DO NOT use adaptors, multiple sockets or reducers.

Caution

CTSV srl declines all responsibility for any damage caused by repairs, modifications and combinations with other equipment, made without the consent of our technical staff.

Caution

Any electrical circuit diagrams and / or lists of component parts will be provided upon request by our technical staff.

Procedure

1. You need just a small amount of biological tissue. In case of abundant quantity of material (surgical) eliminate as far as you can, fat and necrotic tissue, fragmenting the sample into pieces of about 2.5 mm and insert into the disposable capsule **RIGENERACONS** with about 1ml of physiological saline solution.

2. Insert the **RIGENERACONS** into the device **RIGENERA** so that the READY yellow led turns on. Now start the device by turning the lever to the RUN position.

3. After the set time, set the lever to the STANDBY position. 1 to 2 minutes are generally required to disaggregate 3g of tissue. If the disintegration was not complete, you can shift again the **RIGENERACONS** and continue operating the disintegration setting RUN again.

4. Remove the **RIGENERACONS**, turn the cap releasing the hole "syringe connection" then apply a 30ml syringe into the slot, then extract the suspension and deposit it in a test tube or in a suitable container.

Caution

To optimize a routine treatment, it is suggested to evaluate on a sample the optimal time related to the particular tissue that you will process.

Sezione G
maintenance
G.01

Introduction

It is compulsory to perform the cleaning operations with the main switch turned off.

When washing the machine, protect components and electrical connections, since the use of direct jets under pressure on equipment and electrical connections may damage them.

Every 12 months

- check/replace applied labels
- check and verify the correct working

Caution

If it is necessary to leave the **Biological Tissue Disgregator** inactive for a period exceeding 12 months, before reusing it is essential controlling the working of all control devices.
In case of malfunction or breaking, the machine will be replaced (Free of charge if the warranty is valid.)

Fuse Replacement

To replace the fuses (activity executable by operator) of the device **RIGENERA**:

1. turn off the device **RIGENERA** and remove the power cord

2. with a screwdriver 6mm remove the fuse holder pushing and rotating by 45° counterclockwise (n° 3 of the figure shown in Section E1).

3. replace blown fuses with fuses F. 5x20mm 100mA

4. replace the fuse holder in the device **RIGENERA**

5. with the same screwdriver, turn the cap of the fuse holder 45° clockwise;

6. re-insert the power cord and turn on the device **RIGENERA**; the green LED (n° 5 of the figure in section E1) should illuminate.

Final disposal

The **Biological Tissue Disgregator** when out of use should be given to centers authorized by the laws in force at the disposal of waste of the same type (Electrical Devices).

CTSV s.r.l.

DECLARATION OF CONFORMITY

The company CTSV S.r.l., with headquarter in Via Marco Polo, 28 - 10090 Bruino (TO)
and registered office in Via Cipro, 1 - 20124 Brescia,
declares that the machine named below conforms to the essential requirements
as provided by the European Directive 98/79/EC, and subsequent modifications,
relating to the in vitro diagnostic (IVD).

Furthermore, it respects the provisions of the following directives:

2006/95/CE (Low Voltage Equipment Directive)
EMC2004/108/CE (Directive on Electromagnetic Scattering)

machine type: **Biological Tissue Disintegrator**
trading name: **RIGENERA**
manufacturer: **CTSV s.r.l.**
model: **79210R**

C.E.O.

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CTSV srl

Via Marco Polo, 28 - 10090 Bruino (TO) - ITALY

info@ctsv.it - www.ctsv.it

exclusively for:

Human Brain Wave srl

offices and laboratories: Via Balangero, 6 - 10149 Torino - ITALY

telephone: +39 011 793.59.86 - *mobile:* +39 335.806.99.66

info@hbwsrl.com - www.hbwsrl.com